Remarks

Claims 1-58 are pending. Applicants have elected to prosecute Claims 1-7 and 15-33 pursuant to a restriction requirement.

Oath/Declaration

The Examiner asserts that the oath or declaration is defective because the signature of Ralf Rosskamp has not been set forth. Applicants contend that the signature of Ralf Rosskamp was set forth on the declaration submitted to the USPTO. Applicants include herewith a copy of that declaration. Applicants respectfully request that the objection to the declaration be withdrawn.

Drawings

The Examiner stated that the subject matter of the application admits of illustration by a drawing to facilitate understanding of the drawing. Apparently, the Examiner believes that a drawing is missing but the Examiner failed to point out where the omission occurred. Applicants do not believe that a drawing has been omitted but would appreciate further clarification from the Examiner on this point.

Specification

The Examiner noted the presence of blank pages on page 18 and page 24 of the specification. Applicants have removed the blank pages per Examiner's request. The deletion of the blank space has affected the pagination of the specification.

The Examiner objected to the disclosure because it did not include a "Brief Description of Drawings" section. The Examiner required a listing of all figures by number and a corresponding statement explaining what each figure depicts. This listing can be found in the Amendment to Specification section herein.

The figure on original page 17 of the specification (replacement sheet submitted herewith to be inserted at the back of the specification) has been renamed "Figure I". The figure on original page 19 of the specification (replacement sheet submitted herewith to be inserted at the back of the specification) has been renamed "Figure II".

Claim Rejections – 35 USC §112

Claims 22–23 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

In rejection, the Examiner contends that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner asserts that Claims 22-23 fail to meet the requirement for adequate written description of the claimed invention. The Examiner further asserts that there is no reduction to practice of the claimed invention. He states that there are no figures indicating a reduction in lipids and that, for the treatment of atherosclerosis, the results from the proposed clinical studies are expected.

Applicants respectfully disagree with the Examiner's objection to the specification and rejection of claims – for failing to provide an enabling disclosure. As the CCPA observed with respect to 35 U.S.C. §112, first paragraph.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."
In re Marzocchi, 439 F.2d 220, 223; 169 USPQ 367, 369 (CCPA 1971).

Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince a person of ordinary skill in the art of the asserted utilility of the invention. In re Bundy, 642 F.2d 430, 433; 209 USPQ 48, 51 (CCPA 1981). Furthermore, applicants submit that while the Law requires that the specification enable one skilled in the art to make and use the invention, the Law does not require exemplification, data, or tests. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. In re Marzocchi, *supra*. All that is required

is that the specification teach how to make and use the invention without undue experimentation. Applicants submit that this has been done.

The specification of the instant application clearly states that insulin glargine can be used to treat atherosclerosis (page 25, line 15). The specification also provides a disclosure of the testing which can be used by art workers to demonstrate the effects of the agent (page 26, paragraph beginning on line 9). The doses required for administration are disclosed on page 26 in the paragraph beginning on line 18. Specific daily doses and methods of administration are within the ability of one skilled in the art to determine without undue experimentation.

The Examiner points out that no working example defining the treatment of a human is disclosed. Applicants contend that the Examiner is confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. See In re Brana, *supra*. At 1442, quoting Scott v. Finney, 34 F. 3d 1058, 1063, 2 USPQ2d 1115, 1120 (CAFC 1994).

Moreover, it is well-established that proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utilility. As put forth by the CCPA in In re Krimmel:

"We hold as we do because it is our firm conviction that one who has taught the public that a compound exhibits some desireable pharmaceutical property in a standard experimental animal has made a significant contribution to the art, *even though it may eventually appear that the compound is without value in the treatment of humans*." (Emphasis added)

In re Krimmel, 292 F.2d 948, 953; 130 USPQ 215, 219 (CCPA 1961). Furthermore, the fact that syntheses would have to be carried out and bioassays conducted in order to determine the level of activity of a given compound within the scope of the claims does not constitute „undue experimentation," particularly in an art where the level of skill is so high. In re Wands, 8 USPQ2d 1400 (CAFC 1988).

The results of the HOE901 study provide adequate support for Applicants' contention that treatment with long acting insulin, particularly insulin glargine, would safely and effectively retard atherosclerosis progression in patients with EGF, IFG or Type 2 diabetes, particularly early Type 2 diabetes, by improving glycemic control.

Even if applicants' specification were deficient in showing how to use the compounds as atherosclerotic agents, the Examiner has still presented no evidence whatsoever why one of ordinary skill in the art would doubt the antiatherosclerotic activity of long acting insulins, particularly insulin glargine. Therefore, in the absence of a reason supplied by the Examiner to doubt the objective truth of the statements of antiatherosclerotic activity and treatment of dyslipidemia made by applicants' disclosure, the Patent Office must accept the disclosure of the present application as fully enabling with respect to the use of the compounds as recited herein. Therefore, the rejection of claims 22-23 under 35 U.S.C. §112, first paragraph for failing to teach how to use the claimed compounds is improper and should be withdrawn.

Claims 1-7, 15-21, also stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

Applicants repeat the many of the arguments set forth above regarding the enablement rejection of Claims 22-33. Applicants submit that while the Law requires that the specification enable one skilled in the art to make and use the invention, the Law does not require exemplification, data, or tests. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. In re Marzocchi, *supra*. All that is required is that the specification teach how to make and use the invention without undue experimentation. Applicants submit that this has been done.

The specification of the instant application clearly states that long acting insulin, particularly insulin glargine, can be used to treat IGT and early Type 2 diabetes (page 13, lines 6-7 and page 13, lines 16-17. The doses required for administration are disclosed on page 26 in the paragraph beginning on line 18. Specific daily doses and methods of administration are within the ability of one skilled in the art to determine without undue experimentation.

The Examiner points out that no working example defining the treatment of a human is disclosed. Applicants contend that the Examiner is confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption.

Claims 22-33 also stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Once again, Applicants repeat many of the arguments set forth above.

While the Law requires that the specification enable one skilled in the art to make and use the invention, the Law does not require exemplification, data, or tests. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. In re Marzocchi, *supra*. All that is required is that the specification teach how to make and use the invention without undue experimentation. Applicants submit that this has been done.

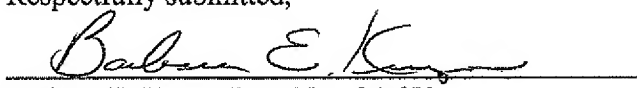
The specification of the instant application clearly states that long acting insulins, particulary insulin glargine, can be used to treat atherosclerosis (page 25, line 15). The specification also provides a disclosure of the testing which can be used by art workers to demonstrate the effects of the agent (page 26, paragraph beginning on line 9). The doses required for administration are disclosed on page 26 in the paragraph beginning on line 18. Specific daily doses and methods of administration are within the ability of one skilled in the art to determine without undue experimentation.

The Examiner points out that no working example defining the treatment of a human is disclosed. Applicants contend that the Examiner is confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. See In re Brana, *supra*. At 1442, quoting Scott v. Finney, 34 F. 3d 1058, 1063, 2 USPQ2d 1115, 1120 (CAFC 1994).

Conclusion

In view of the amendment to the specification and the remarks herein, Applicants respectfully submit that the pending rejection should be withdrawn and the application allowed.

Respectfully submitted,



Barbara E. Kurys, Reg. No.: 34,650
Attorney/Agent for Applicant

sanofi-aventis U.S. LLC
U.S. Patent Operations
Route #202-206 / P.O. Box 6800
Bridgewater, New Jersey 08807-0800
Telephone: 908-231-2965
Telefax: 908-231-2626

sanofi-aventis Docket No. USAV2003-0012 US NP